

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION**

Trans-Radial Solutions, LLC

Plaintiff,

v.

Burlington Medical, LLC, Mr. John Williams,
Fox Three Partners, LLC, and Phillips Safety
Products, Inc.

Defendants.

Case No. 2:18-cv-00656- RAJ-DEM

**DEFENDANTS' RESPONSE TO PLAINTIFF'S RULE 72 OBJECTION
TO RULING EXCLUDING CERTAIN EXPERT OPINIONS OF
DR. KENNETH GALL AND DR. JENNIFER VANDERHART**

Defendants Burlington Medical, LLC (“Burlington”), Fox Three Partners, LLC (Fox Three”), and Phillips Safety Products, Inc. (“Phillips”) (collectively “Defendants”) submit this Response to Plaintiff’s Rule 72 Objection (“Objection”) to the order entered by Magistrate Miller on May 20, 2020, excluding unsupported damages opinions offered by Plaintiff’s two proposed experts, Kenneth P. Gall, Ph.D. and Dr. Jennifer Vanderhart, Ph.D. Dkt. 200 (Order). Plaintiff’s Objection (Dkt. 208 & 209) rehashes arguments already thoroughly addressed and correctly rejected by Magistrate Miller, and it should be denied.

INTRODUCTION

Plaintiff’s Objection to Magistrate Miller’s decision ignores an avalanche of facts that contradict the wildly inflated market projections offered by Plaintiff’s experts (including dismal sales data, negative feedback from would-be customers, and market contentment with similar decades-old products), and does nothing to rebut Magistrate Miller’s well-founded conclusion that the opinions at issue are unreliable. Magistrate Miller correctly ruled that Dr. Gall’s market projections should be excluded because Dr. Gall is not qualified to opine on projected product sales, because his projections are not based on reliable methods, and because he did not rely upon sufficient facts and data. Dkt. 200 at 1; *see also* Fed. R. Evid. 702. Magistrate Miller likewise correctly excluded Dr. Vanderhart’s speculative damages calculations, which rely mainly on Dr. Gall’s unreliable market projections. *Id.* at 2-3.

Magistrate Miller correctly excluded Dr. Gall’s market projections because the methods used to generate those projections are unreliable, and indeed, undiscernible. *See, e.g.*, Ex. A¹ (May 12, 2020 hearing transcript) at 22:12-21; *Id.* at 26:3-5 (“There is no model. He just said 70 percent,

¹ Exhibits A-D are submitted with this Response. Other previously-filed exhibits are referenced by docket number.

a hundred percent. There isn't anything there. He hasn't offered any basis for how he got to those numbers.") Plaintiff now seeks to obfuscate that conclusion with repetitive laundry lists of vague statements, none of which explain what methodology Dr. Gall actually applied, let alone why it was reliable. *See* Dkt. 208 at 9-11. Indeed, Dr. Gall showed disdain for his obligation to assist the jury by employing reliable methods. When asked if he could identify any treatise or text that would support his opinion, for example, he responded: "It would not surprise me if there were such reports. Harvard Business School turns out case reports like farmers turn out corn, so I'm sure we could find one. I cannot cite one for you." Dkt. 108-5 (Gall Dep.) at 155:7-13.

Magistrate Miller also correctly struck Dr. Gall's market projections because they are not supported by reliable facts and data. Dr. Gall's opinion that the Rad-Guard should have experienced near-universal market demand ignores *actual* sales data for the products at issue, which shows Plaintiff only sold 22 Rad-Guards over the past five-plus years.² *See* Dkt. 108-3 (A. Shealy Dep.) at 12:25-13:4. Defendant Burlington similarly only sold 32 of its own IV mounted barriers during the three years it was on the market. Dkt. 108-4 (BML_0001) (IV mounted barrier sales). Dr. Gall also failed to conduct any market research, perform any surveys, or review any publications to obtain support for his opinion. *See, e.g.*, Dkt. 108-5 at 108:11-15; *Id.* at 155:7-13.

Plaintiff argues that a jury should nonetheless be allowed to consider Dr. Gall's unfounded opinions and determine what weight they deserve. *See* Dkt. 208 at 11. That argument runs afoul of well-settled law on the critical gatekeeping role played by trial courts when assessing expert testimony, however. *See Nease v. Ford Motor Co.*, 848 F.3d 219, 231 (4th Cir. 2017) (reversing district court's finding that "reliability arguments simply go to the weight the jury should afford"

² Plaintiff sells essentially two products—a radiation barrier that can clamp to a pole, called Rad-Guard, and a larger and more expensive table-top system, called Cardio-Trap.

to expert testimony, as that would improperly “delegate the court’s gatekeeping role to the jury.”) (quotation marks omitted). Allowing Dr. Gall’s unreliable opinions to go to the jury would be particularly problematic here because Dr. Gall seeks to present graphs that misleadingly suggest he used real data in an objective formula to reach his opinions, when in truth those graphs are just “standard” S-curves that were not generating using any actual data on the products at issue. *See* Dkt. 209-2 (Gall Report) ¶ 68; *Id.* ¶ 72; Ex. A at 11-16.

Magistrate Miller also correctly held that Dr. Gall lacks the necessary expertise to opine on projected product sales. Dr. Gall has never previously been asked to serve as an expert regarding sales or marketing, and he has no formal training in those fields. Dkt. 108-5 at 155:20-23 (“Q. Have you ever been asked to provide any opinion, expert opinion on marketing or sales before? A. I have not.”); *Id.* at 15:23-24 (“I have not received any degrees in business from an educational institution.”) Dr. Gall also admitted that he never worked in cardiac catheterization labs—the primary market for the products at issue. Dkt. 208-1 (Gall CV) at 1-2; Dkt. 108-5 at 37:24-38:4 (“I have not worked directly in the cardiac catheterization lab, other than to observe procedures.”). While Plaintiff is emphatic that Dr. Gall has had thirty years of experience “buying, selling, and using” radiation protection devices, Dr. Gall’s “involvement” with purchasing medical equipment for hospitals ceased over 15 years ago. *See* Dkt. 208-1.

Given these glaring problems, it is no surprise that Plaintiff strains to challenge Magistrate Miller’s carefully considered decision, and ultimately resorts instead to contradicting its own prior briefing. For example, Plaintiff’s prior briefing emphasized Dr. Gall’s supposed familiarity with two specific products—a dosimeter array sold by Sun Nuclear, and a laser positioning system sold by Gammex. *See* Dkt. 115 (Pl. Opp. to Motion to Strike) at 11 (discussing Dr. Gall’s deposition testimony regarding “Sun Nuclear dosimeter array and Gmax [*sic*] lasers” as support for his

opinions); *Id.* at 22 (“Dr. Gall specifically considered other medical products that have been able to do the same thing through patent protection. He cited, among others, Gmax [*sic*] lasers. . .”). Plaintiff’s prior briefing also emphasized Dr. Gall’s work as an inventor. *See, e.g.*, Dkt. 115 at 23 (“Dr. Gall has been personally involved in developing and marketing his own radiation products to hospital customers.”). Magistrate Miller enquired further about those examples during the May 12, 2020 hearing, before holding that:

Dr. Gall’s personal involvement in the design and marketing of a complex radiation therapy system which sold for \$28 million per unit provides no basis for his opinion for future sales of the Rad-Guard device which sold for less than \$1,000.00. His anecdotal reference to two other products during his deposition did not appear to inform his disclosed expert opinion on future sales of the Rad-Guard as he was unable to offer any documentation or evidence related to either product or to any other similar product which might support his hypothetical projections.

Dkt. 200 (Order) at 1-2.

Remarkably, Plaintiff now takes issue with Magistrate Miller for addressing Plaintiff’s own prior arguments, complaining “no part of [Dr. Gall’s] opinion depends on Dr. Gall’s ‘personal involvement in the design and marketing of a complex radiation therapy system which sold for \$28 million per unit’ or the ‘two other products’ discussed in his deposition.” Dkt. 208 at 8. What, then is to be made of Plaintiff’s own prior briefing and Dr. Gall’s sworn deposition testimony to this effect? *See, e.g.*, Dkt. 115 at 22 (“Dr. Gall specifically considered other medical products that have been able to do the same thing through patent protection. He cited, among others, Gmax [*sic*] lasers. . .”) (quoting Gall Dep. at 143:15-19); *Id.* at 23. Having disavowed its prior arguments, Plaintiff is now left with *essentially nothing* to support Dr. Gall’s opinions, apart from Plaintiff’s unrealistic demands, and Dr. Gall’s subjective beliefs. *See, e.g.*, Dkt. 108-5 at 151:7-10 (admitting that even his “100 percent market of 10,000 units, not surprisingly, has been criticized as ridiculously low” by Plaintiff’s owner and CFO); *Id.* at 137:23-138:5.

Magistrate Miller carefully assessed Plaintiff's arguments before properly excluding Dr. Gall's unqualified and methodologically baseless sales projections, and the related damages opinions advanced by Plaintiff's second expert, Dr. Vanderhart. The arguments raised in Plaintiff's Objection have already been briefed at length, and addressed in detail by Magistrate Miller. *See* Dkt. 107, 108, 115, 119, 127 & 129 (Motion to Strike briefing); *see also*, Ex. A (hearing transcript). Enough ink has already been spilled on Plaintiff's implausible and methodologically unsound damages theory. Plaintiff's Rule 72(a) Objection should accordingly be denied.

LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence "imposes a special gatekeeping obligation on the trial judge to ensure that an opinion offered by an expert is reliable." *Nease*, 848 F.3d at 230. A party seeking to rely on expert testimony "must establish its admissibility by a preponderance of proof." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n. 10 (1993)). In particular, "[e]xpert testimony must be 'based on sufficient facts or data,' and the expert must arrive at his opinions by properly applying 'reliable principles and methods' to the facts." *Hickerson v. Yamaha Motor Corp.*, 882 F.3d 476, 480-81 (4th Cir. 2018) (quoting Fed. R. Evid. 702). Expert testimony that is merely "subjective belief or unsupported speculation" does not meet that standard, and must be excluded. *Daubert*, 509 U.S. at 590; *Nease*, 848 F.3d at 230.

Rule 72(a) provides that a party may object to a magistrate judge's ruling on any non-dispositive issue. Fed. R. Civ. P. 72(a). When considering objections pursuant to Rule Fed. R. Civ. P. 72(a), district courts apply a "clearly erroneous or contrary to law" standard. *Id.* "Only if a magistrate judge's decision is 'clearly erroneous or contrary to law' may a district court judge modify or set aside any portion of the decision." *Louis Vuitton Malletier v. Haute Diggity Dog*,

2007 U.S. Dist. LEXIS 14244, at *4 (E.D. Va. Feb. 28, 2007). A decision is clearly erroneous when the “reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.” *Id.* (quoting *U.S. v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948)).

ARGUMENT

Magistrate Miller properly fulfilled the court’s role as a gatekeeper by excluding proposed expert opinions that are based on no more than “subjective belief or unsupported speculation.” *Daubert*, 509 U.S. at 590. Magistrate Miller’s order is amply supported by the record, and it is neither “clearly erroneous” nor “contrary to law.” Fed. R. Civ. P. 72(a). Plaintiff’s Objection should accordingly be denied, and Magistrate Miller’s order should be affirmed.

I. DR. GALL’S MARKET PROJECTIONS ARE UNRELIABLE AND UNSUPPORTED

Magistrate Miller properly excluded Dr. Gall’s implausible market projections “because those projections are not based on any reliable data or method, and because he otherwise lacks the necessary qualifications, education, training, and experience to opine generally on lost future sales of the product.” Dkt. 200 at 1. Magistrate Miller’s conclusion is well founded since Dr. Gall’s market projections lack “the markers of reliability Rule 702 and *Daubert* require to prevent an expert from misleading a jury with unproven conjecture.” *Hickerson*, 882 F.3d at 482 (upholding exclusion of expert opinion unsupported by “research, data, or scientific theories.”).

Plaintiff erroneously argues that any concerns regarding Dr. Gall’s opinions should instead be addressed through “cross-examination at trial,” claiming “[u]nder the analysis applied just three years ago in *Bresler*, exclusion of Dr. Gall’s market opinions will likely lead only to a second trial.” Dkt. 208 at 11 (citing *Bresler v. Wilmington Tr. Co.*, 855 F.3d 178 (4th Cir. 2017)). Plaintiff’s criticism of Magistrate Miller’s order based on the holding in *Bresler* is misguided.

In *Bresler*, the Fourth Circuit, applying the deferential standard used when reviewing

evidentiary decisions, upheld a trial court’s decision to admit expert testimony. *Bresler*, 855 F.3d at 195 (holding “that although [expert] Pugh’s testimony was unclear at various points during the trial, the district court did not abuse its discretion in declining to exclude Pugh’s testimony under *Daubert*.”) The expert at issue in *Bresler* was an accountant, who used established formulas to conduct a complex damages calculation. *Bresler*, 855 F.3d at 188. Here, in contrast, Plaintiff’s proposed expert lacks any formal training in marketing or sales. *See, e.g.*, Dkt. 108-5 at 15:23-24 (“I have not received any degrees in business from an educational institution.”). And instead of employing a well-understood formula to reach his opinion—as the accounting expert did in *Bresler*—Dr. Gall used no accepted methodology at all to calculate purported future sales. *See, e.g.*, Dkt. 108-5 at 155:7-13; Ex. A at 26:3-5 (Magistrate Miller explaining: “There is no model. He just said 70 percent, a hundred percent. There isn’t anything there. He hasn’t offered any basis for how he got to those numbers.”)

Nothing in *Bresler* supports Plaintiff’s argument that Dr. Gall’s flawed and unfounded opinions should be presented to the jury and tested through cross-examination. Indeed, that argument ignores voluminous prior precedent. As the Fourth Circuit explained just three years ago, “[t]he district court’s ‘gatekeeping function’ under *Daubert* ensures that expert evidence is sufficiently relevant and reliable *when it is submitted to the jury*.” *Nease*, 848 F.3d at 231 (emph. in original). It is reversible error for a trial court to abandon its gatekeeping role and shift the burden to the jury to determine the reliability after an expert’s opinion. *Id.* (holding “the district court did not perform its gatekeeping duties” because “[t]he fact that an expert witness was subject to a thorough and extensive examination does not ensure the reliability of the expert's testimony”) (quotation marks omitted); *see also Lipitor (Atorvastatin Calcium) Mktg. v. Pfizer, Inc.*, 892 F.3d 624, 634 (4th Cir. 2018) (affirming exclusion of expert opinion as unreliable when the opinion

was based on a result-driven analysis using cherry-picked data); *Small v. WellDyne, Inc.*, 927 F.3d 169, 177 (4th Cir. 2019) (“[I]t is not enough for an expert to rely on his subjective belief. [] Without testing, supporting literature in the pertinent field, peer reviewed publications or some basis to assess the level of reliability, expert opinion testimony can easily, but improperly, devolve into nothing more than proclaiming an opinion is true ‘because I say so.’”)

None of these recent Fourth Circuit cases are in tension with *Bresler*, and all of them support, and indeed require, the exclusion of the unfounded expert opinions at issue here.

A. Dr. Gall’s Market Projections Do Not Utilize Any Established Methodology

Magistrate Miller correctly held that “Dr. Gall may not offer his projections for Rad-Guard’s hypothetical market penetration and lost future sales because those projections are not based on any reliable data or method[.]” Dkt. 200 at 1. Plaintiff now contends that “[t]here is no plausible way that Dr. Gall’s opinions should be excluded for lack of reliable data or methods.” Dkt. 208 at 7. None of the nine factors that Plaintiff conjures in support of that contention speak to the reliability of any principle or method employed by Dr. Gall, however. *See* Dkt. 208 at 9-10.

Plaintiff claims, for example, that Dr. Gall’s opinion regarding “the number of Rad-Guards each cath lab likely would purchase during its 10-year equipment procurement cycle; *i.e.*, 5 units on average over 10 years” is supported by “the spreadsheet [Dr. Gall] attaches to his report showing Burlington itself sold 8 of its infringing product to a single hospital system in just 3 years.” Dkt. 208 at 9. As an initial matter, *there is no spreadsheet* attached to Dr. Gall’s report. *See* Dkt. 209-2 (Gall Report) at p. 28 (listing the exhibits to Dr. Gall’s report). The document referenced by Plaintiff is instead *Gall Deposition* Ex. 5 (BML_00001), which Dr. Gall does not appear to have relied on when preparing his report. *See* Dkt. 108-5 at 115:5-117:4. In any event, while BML_00001 does indeed show that one facility—New Hanover Regional Medical Center—

purchased eight IV mounted barriers from Burlington, that same spreadsheet also shows that *only thirteen different facilities ever purchased IV mounted barriers at all*, resulting in total sales of a whopping 32 barriers. *See* Dkt. 108-4 (BML_00001).³ That data does not remotely support Dr. Gall's prediction of near universal demand for IV mounted barriers. Indeed, it does not even support Dr. Gall's opinion regarding the average number of Rad-Guards each facility would purchase, since Dr. Gall opined each facility would, on average, purchase five units, while BML_00001 shows each facility purchased, on average, under 2.5 units. *Id.*

Dr. Gall's belief in "near universal demand" for the Rad-Guard is also contradicted by a great deal of other evidence. *See, e.g.*, Dkt. 129-1 at TRS_003949 (TRS Rad-Guard Q&A script explaining "You can't expect every lab to buy one for each room but you can expect more to be used if you give them away."); Ex. B (Feb. 13, 2017 email to Plaintiff's new sales representative) at TRS_004109 (listing reasons customers have given for not buying Rad-Guards, including: "They can't see through the Rad-Guard"; and "We don't really need the Rad-Guard."). Even Dr. Gall's observation regarding 10-year hospital equipment procurement cycles applies only to major medical equipment according to Dr. Gall, and not to the purchase of "ancillary" equipment like Rad-Guards. *See* Dkt. 209-2 (Gall Report) ¶ 63. And Dr. Gall's belief that there are no non-infringing alternatives to the Rad-Guard is simply false. *See, e.g.*, Dkt. 108-7 at TRS_003042 (August 2018 email to Plaintiff stating "We haven't seen a lot of interest in Rad-Guard because our hospitals have other mobile barriers that they use.").

This is not mere quibbling about the values an expert chooses to use in a well-understood equation, as was the case in *Bresler*, 855 F.3d at 195-96. Unlike the accounting expert in *Bresler*,

³ Plaintiff has also now acknowledged one of the final two IV mounted barriers ever sold, which was purportedly purchased by "Lindsay Graham" in South Carolina, was in fact ordered at the direction of Plaintiff. *See* Defs.' MSJ (Dkt. 159) Ex. 14 (R. Shealy Dep.) at 19:9-21:3.

Dr. Gall's opinions rely on no established methodology at all. *See, e.g.*, Ex. A at 22:12-21 (“[T]he question that has to be answered in this hearing is whether [Dr. Gall] based his opinion on sufficiently reliable methods or data such that it will be helpful to the jury, and I can’t see it. I don’t see what he even based it on.”). There is no calculation to even review here, because Dr. Gall did not perform any calculations at all, apart from multiplying the number of cardiac catheterization labs by five. Instead, Dr. Gall presents his purely subjective belief about market demand for Rad-Guard, which was driven by Plaintiff’s demands in this litigation. *See, e.g.*, Dkt. 108-5 at 151:7-11(acknowledging even “my 100 percent market of 10,000 units, not surprisingly, has been criticized as ridiculously low” by Plaintiff).

“Expert testimony must be ‘based on sufficient facts or data,’ and the expert must arrive at his opinions by properly applying ‘reliable principles and methods’ to the facts.” *Hickerson*, 882 F.3d at 481 (citing Fed. R. Evid. 702). Like the expert who was properly excluded in *Tyger Constr.*, Dr. Gall’s opinions instead rely on assumptions that are demonstrably counterfactual. *Tyger Constr. Co. v. Pensacola Constr. Co.*, 29 F.3d 137, 143 (4th Cir. 1994). Magistrate Miller thus properly excluded Dr. Gall’s unfounded opinion regarding hypothetical Rad-Guard sales.

B. Dr. Gall’s Opinion Regarding Lost Future Sales is Equally Unfounded

The support for Dr. Gall’s related opinion regarding lost future Rad-Guard sales is likewise pure fantasy. Plaintiff cites six factors that supposedly support Dr. Gall’s opinion that as a result of Defendants’ actions, Plaintiff will sell 7,000 Rad-Guards over twenty years (70% market penetration), instead of selling 10,000 units over ten years (100% market penetration). Dkt. 208 at 10. None of the six factors listed by Plaintiff provide a reliable foundation for Dr. Gall’s opinion.

Plaintiff argues that Dr. Gall first “identifies the considerable problems that the Rad-Guard now faces as a result of the Defendants’ actions.” Dkt. 208 at 10 (citing p. 25 of Dr. Gall’s report).

The full extent of what Dr. Gall *actually says* on that topic at page 25 of his report, however, is as follows: “Under conditions of interrupted or interfered-with sales with a simultaneous introduction of a similar but inferiorly performing infringing product, the market performance of the RadGuard would be considerably diminished.” Dkt. 209-2 (Gall Report) ¶ 70. That is pure speculation, and counterfactual to boot, since Burlington’s IV mounted barriers *were not* introduced to the market at the same time as Rad-Guard, nor is there any reliable evidence that the few facilities who actually purchased IV mounted barriers were unhappy with their performance. *See, e.g.*, Dkt. 108-5 at 150:3-11 (“Q. What is the basis for your belief that the market was negatively impacted by the reputation of Burlington's product? A. So I certainly read somewhere that there was some product which was sent back for delamination or something like that.”); Ex. C (Pl.’s Resp. to 2nd Req. for Production) at 2, Req. No. 37 (confirming there are no documents supporting Plaintiff’s contention that the IV mounted barriers sold by Burlington generated negative publicity in the industry).

The remaining five factors are no more illuminating. The fourth factor, for example, suggests Dr. Gall’s opinion is supported because “the reduction to 70%” market share is “neither the most optimistic scenario nor the least optimistic scenario.” Dkt. 208 at 10. The fact that Dr. Gall could have arbitrarily picked a higher or lower number instead of landing on 70% does nothing to demonstrate that his opinion is the product of any reliable methodology, however. *See, e.g.*, Ex. A at 26:3-5. The fifth listed factor is similarly circular, and unhelpful. It states that Dr. Gall “confirm[ed] the appropriateness of the 70% figure in deposition testimony as based on the factors above and his considerable experience in the industry.” Dkt. 208 at 10 (citing Gall Dep. at 139:23-141:14 & 142:24-144:12). The cited portions of Dr. Gall’s deposition, however, address the two purportedly similar products that Magistrate Miller already specifically addressed, and correctly found to be unhelpful. Dkt. 200 at 1-2 (stating Dr. Gall’s “anecdotal reference to two

other products during his deposition did not appear to inform his disclosed expert opinion on future sales of the Rad-Guard as he was unable to offer any documentation or evidence related to either product or to any other similar product which might support his hypothetical projections.”).

Tellingly, when Dr. Gall was asked if he could identify any treatise or text that provides support for his conclusion that Burlington’s sale of just 32 IV mounted barriers, to just thirteen institutions, would depress Rad-Guard sales for the next twenty years, leading to the loss of thousands of Rad-Guard sales, he stated: “It would not surprise me if there were such reports. Harvard Business School turns out case reports like farmers turn out corn, so I’m sure we could find one. I cannot cite one for you.” Dkt. 108-5 at 155:7-13. Neither *Bresler*, nor *Daubert*, nor *Kumho*, nor any other case cited by Plaintiff, permits this kind of rank speculation in the guise of expert testimony. *See, e.g., Nease*, 848 F.3d at 231 (“One especially important factor for guiding a court in its reliability determination is whether a given theory has been tested.”); *Cooper*, 259 F.3d at 202 (“if an expert utterly fails to consider alternative causes or fails to offer an explanation for why the proffered alternative cause was not the sole cause, a district court is justified in excluding the expert’s testimony.”).

As the Fourth Circuit recently reiterated: “Expert witnesses have the potential to be both powerful and quite misleading.” *Small*, 927 F.3d at 176 (quotation marks omitted). Trial courts must accordingly confirm that a “proffered expert opinion is ‘based on scientific, technical, or other specialized knowledge and not on belief or speculation.’” *Nease*, 848 F.3d at 229 (quoting *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999)). “It is not enough for an expert to rely on his subjective belief. Without testing, supporting literature in the pertinent field, peer reviewed publications or some basis to assess the level of reliability, expert opinion testimony can easily, but improperly, devolve into nothing more than proclaiming an opinion is true ‘because I

say so.” *Small*, 927 F.3d at 177. Dr. Gall’s proposed opinions regarding future Rad-Guard sales do exactly that, and were thus properly excluded.

C. Dr. Gall is Not an Expert in Marketing or Sales

Magistrate Miller’s conclusion that Dr. Gall “lacks the necessary qualifications, education, training, and experience to opine generally on lost future sales” (Dkt. 200 at 1) is likewise amply supported by the record and controlling law. Dr. Gall has no formal training in sales or marketing, and he has never previously been asked to testify regarding sales projections, nor has he ever written, taught, or presented on that topic. *See* Dkt. 108-5 at 15:23-24 (“I have not received any degrees in business from an educational institution.”); *Id.* at 155:20-156:3 (“Q. Have you ever been asked to provide any opinion, expert opinion on marketing or sales before? A. I have not.”) His training and education are in nuclear physics, not sales or marketing. Dkt. 208-1 (Gall CV).

Plaintiff complains that Magistrate Miller did not sufficiently consider Dr. Gall’s role in hospital procurement. But Dr. Gall’s experience working in hospitals where he helped to make purchasing decisions, which ended over 15 years ago, does not qualify him to opine on the purchasing decisions to be made by every cardiac catheterization laboratory in the United States over the next ten to twenty years. *See, e.g., Xpert Universe, Inc. v. Cisco Sys.*, No. 09-cv-157, 2013 U.S. Dist. LEXIS 31327 (D. Del. Mar. 7, 2013) (rejecting proposed expert testimony on projected future sales when plaintiff’s expert possessed expertise in computer science, but not “market performance” and “commercial success”). Dr. Gall admits, moreover, that he has never even worked in a cardiac catheterization lab—the primary market at issue. Dkt. 108-5 at 37:24-38:7.

Plaintiff argues that Magistrate Miller “ignores all of Dr. Gall’s consulting work assessing market conditions for radiological product lines, including devices that sell for thousands of dollars, not tens of millions.” Dkt. 108 at 12 (citing Gall Dep. at pp. 18-19). The full extent of Dr.

Gall testimony on that topic, however, reads as follows: “I provide technical consulting to medical device manufacturers. I have provided startup business development consulting to large Chinese firms that wanted to establish a foothold in the United States.” Dkt. 108-5 at 18:21-19:2. Nothing in that cursory response suggests that Dr. Gall’s consulting work involved evaluating the expected sales of products similar to Rad-Guard, let alone demonstrates he is capable of doing so reliably.

The proponent of expert testimony bears the burden of establishing that testimony is admissible by a preponderance of the evidence. *Cooper*, 259 F.3d at 199. Cryptic references to consulting during a deposition fall far short of meeting that burden. Dkt. 108-5 at 18:21-19:2. Magistrate Miller’s conclusion that Dr. Gall does not have the necessary qualifications, education, training, and experience to opine on protected future Rad-Guard sales is thus again well founded.

II. DR. VANDERHART’S DAMAGES CALCULATION BASED ON LOST FUTURE RAD-GUARD SALES MUST ALSO BE EXCLUDED BECAUSE IT RESTS ON DR. GALL’S UNRELIABLE OPINIONS

Magistrate Miller also properly excluded Dr. Vanderhart’s calculation of Plaintiff’s purported damages from lost future Rad-Guard sales, because those calculations are based on Dr. Gall’s unreliable market projections. Dkt. 200 at 2. As Magistrate Miller explained, “Because the sole basis for Dr. Vanderhart’s opinions on lost Rad-Guard profits derived from future sales is Dr. Gall’s excluded projections of those sales, her opinions on those lost future sales, as well as the present value calculations based on Dr. Gall’s market penetration opinions, lack any reliable basis and must be excluded.” Dkt. 200 at 2. Magistrate Miller’s decision is again amply supported by copious case law excluding damages calculations based on unrealistic assumptions. *See, e.g., Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 21 (2d Cir. 1996) (“Where lost future earnings are at issue, an expert’s testimony should be excluded as speculative if it is based on unrealistic assumptions”); *accord MyGallons LLC v. U.S. Bancorp*, 521 F. App’x 297, 307 (4th Cir. 2013).

III. DR. VANDERHART'S OPINION ON THE NUMBER OF CARDIO-TRAP'S THAT SUPPOSEDLY *SHOULD* HAVE BEEN SOLD IS LIKEWISE UNFOUNDED

Magistrate Miller also properly excluded Dr. Vanderhart's opinion regarding the number of Cardio-Trap systems that Burlington supposedly could have sold if it had only tried harder. Dkt. 200 at 2-3. As an initial matter, none of Plaintiff's causes of action allege Defendants failed to sell a sufficient number of Cardio-Traps. Dkt. 1. Defendants, moreover, had no obligation to sell any set number of Plaintiff's products at all. *See* Dkt. 199 (MSJ Reply) at 2. In any event, Magistrate Miller correctly held that Dr. Vanderhart's "selective citation to opinions of sales representatives is insufficient - standing alone - to support any continuing obligation by Burlington to market the product, or the precise number of units she claims could have been sold." Dkt. 200 at 3.

Plaintiff insists that "[t]he sales team's projections are proper evidence of likely future performance," Dkt. 208 at 14, but Plaintiff fails to rebut Magistrate Miller's conclusion that Dr. Vanderhart's Cardio-Trap sales projections are improperly based on cherry-picked statements from just a few Burlington sales representatives. *See, e.g., Lipitor (Atorvastatin)*, 892 F.3d at 634 ("Result-driven analysis, or cherry-picking, undermines principles of the scientific method and is a quintessential example of applying methodologies (valid or otherwise) in an unreliable fashion.") Among many contrary pieces of evidence not taken into account in Dr. Vanderhart's Cardio-Trap sales projections are Trans-Radial's own prior statements regarding Burlington's success with Cardio-Trap sales, and the experience of multiple other distributors who tried to sell Plaintiff's products, with even less success. *See, e.g.,* Ex. D (Sept. 5, 2018 email from Plaintiff stating "Burlington has done a good job" marketing Cardio-Trap). Magistrate Miller's decision to exclude Dr. Vanderhart's testimony regarding the number of additional Cardio-Trap sales that Burlington purportedly should have made is thus again well founded.

CONCLUSION

Magistrate Miller did not ignore Plaintiff's arguments, weak though they may be, as Plaintiff's unfairly suggests. Dkt. 208 at 10 (claiming "The Magistrate Judge's order is silent as to what part of this is unreliable"). Instead, Magistrate Miller reviewed the relevant expert reports carefully, before reaching the unavoidable conclusion that the opinions at issue are unreliable and must accordingly be excluded. Plaintiff's Objection should thus be denied, and Magistrate Miller's decision should be affirmed for the reasons set forth above.

Dated: June 17, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on June 17, 2020, I electronically filed the foregoing document with the Clerk of the Court, using the Court's ECF system, which will send a "Notice of Electronic Filing" to all attorneys of record in this proceeding.

/s/ Rebecca S. LeGrand
Rebecca S. LeGrand